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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,805	11/14/2005	Tesfaye Biftu	21404P	1696

210 7590 09/17/2008
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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,805	BIFTU ET AL.	
	Examiner	Art Unit	
	Brenda L. Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23,24 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-21,23 and 24* is/are allowed.

6)☒ Claim(s) *28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/27/07; 2/27/06; 8/27/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-21, 23, 24 and 28 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds, compositions and method of use of the compounds of formula (I), does not reasonably provide enablement for the complex compositions of formula I as claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The pharmaceutical compositions of the instant invention where an additional active ingredient such as **a second dipeptidyl peptidase IV inhibitor; an insulin sensitizer selected from the group consisting of a PPARγ agonist, a PPARα/γ dual agonist, a PPARα agonist, a biguanide, and a protein tyrosine phosphatase-1B inhibitor; an insulin or insulin mimetic; a sulfonylurea or other insulin secretagogue; an α-glucosidase inhibitor; a glucagon receptor antagonist; GLP-1, a GLP-1 mimetic, or a GLP-1 receptor agonist; GIP, a GIP mimetic, or a GIP receptor agonist; PACAP, a PACAP mimetic, or a PACAP receptor agonist; a cholesterol lowering agent such as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual**

agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant; a PPARδ agonist; an antiobesity compound; an ileal bile acid transporter inhibitor; an anti-inflammatory agent; and an antihypertensive agent is included in the compositions. The specification does not define that which is intended in the additional active ingredients, i.e. which a second dipeptidyl peptidase IV inhibitor; an insulin sensitizer selected from the group consisting of a PPARγ agonist, a PPARα/γ dual agonist, a PPARα agonist, a biguanide, and a protein tyrosine phosphatase-1B inhibitor; an insulin or insulin mimetic; a sulfonylurea or other insulin secretagogue; an α-glucosidase inhibitor; a glucagon receptor antagonist; GLP-1, a GLP-1 mimetic, or a GLP-1 receptor agonist; GIP, a GIP mimetic, or a GIP receptor agonist; PACAP, a PACAP mimetic, or a PACAP receptor agonist; a cholesterol lowering agent such as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant; a PPARδ agonist; an antiobesity compound; an ileal bile acid transporter inhibitor; an anti-inflammatory agent; an antihypertensive agent, etc.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

a. A second dipeptidyl peptidase IV inhibitor in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a second dipeptidyl peptidase IV inhibitor" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a second dipeptidyl peptidase IV inhibitor.

b. An insulin sensitizer selected from the group consisting of a PPARγ agonist, a PPARα/γ dual agonist, a PPARα agonist, a biguanide, and a protein tyrosine phosphatase-1B inhibitor in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an insulin sensitizer selected from the group consisting of a PPARγ agonist, a PPARα/γ dual agonist, a PPARα agonist, a biguanide, and a protein tyrosine phosphatase-1B inhibitor" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an insulin sensitizer selected from the group consisting of a PPARγ agonist, a PPARα/γ dual agonist, a PPARα agonist, a biguanide, and a protein tyrosine phosphatase-1B inhibitor.

c. An insulin or insulin mimetic in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an insulin or insulin mimetic" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an insulin or insulin mimetic.

d. A sulfonylurea or other insulin secretagogue in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a sulfonylurea or other insulin secretagogue" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a sulfonylurea or other insulin secretagogue.

e. An α-glucosidase inhibitor in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an α-glucosidase inhibitor" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an α-glucosidase inhibitor.

f. A glucagon receptor antagonist in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a glucagon receptor antagonist" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a glucagon receptor antagonist.

g. A GLP-1, a GLP-1 mimetic, or a GLP-1 receptor agonist in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a GLP-1, a GLP-1 mimetic, or a GLP-1 receptor agonist" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a GLP-1, a GLP-1 mimetic, or a GLP-1 receptor agonist.

h. A GIP, a GIP mimetic, or a GIP receptor agonist in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a GIP, a GIP mimetic, or a GIP receptor agonist" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of

formula I and an additional active ingredient, which is a GIP, a GIP mimetic, or a GIP receptor agonist.

i. A PACAP, a PACAP mimetic, or a PACAP receptor agonist in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a PACAP, a PACAP mimetic, or a PACAP receptor agonist" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is a PACAP, a PACAP mimetic, or a PACAP receptor agonist.

j. A cholesterol lowering agent such as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a cholesterol lowering agent such as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition

consisting of the compounds of formula I and an additional active ingredient, which is a cholesterol lowering agent such as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant.

k. A PPARδ agonist in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "a PPARδ agonist" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an PPARδ agonist.

l. An anti-obesity compound in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an anti-obesity compound" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an anti-obesity compound.

m. An ileal bile acid transporter inhibitor in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an ileal bile acid transporter inhibitor" is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an ileal bile acid transporter inhibitor.

n. An anti-inflammatory agent in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an anti-inflammatory agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an anti-inflammatory agent.

o. An antihypertensive agent in claim 28 is a relative terms, which renders the claim indefinite. The specific term of claims 28 "an antihypertensive agent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The nature of the composition consisting of the compounds of formula I and an additional active ingredient, which is an antihypertensive agent.

p. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 28 recites the broad recitation cholesterol lowering agent, and the claim also recites as (i) HMG-CoA reductase inhibitor, (ii) sequestrant, (iii) nicotinyl alcohol, nicotinic acid or a salt thereof, (iv) PPARα agonist, (v) PPARα/γ dual agonist, (vi) inhibitor of cholesterol absorption, (vii) acyl CoA:cholesterol acyltransferase inhibitor, and (viii) anti-oxidant, which is the narrower statement of the range/limitation.

Allowable Subject Matter

3. Claims 1-21, 23 and 24 are allowed. None of the prior art of record or a search in the pertinent art area teaches the compounds, compositions and method of use of the 6,7,8,9-tetrahydro-5*H*-[1,2,4]triazolo[4,3-*d*][1,4]diazepine, 6,7,8,9-tetrahydro-5*H*-[1,2,4]triazolo[4,3-*a*][1,4]diazepine, and 6,7,8,9-tetrahydro-5*H*-imidazo[1,2-a][1,4]diazepine compounds of formula (I) as claimed herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624